

JUL 15 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stephen E. Zale, Paul A. Burke, Howard Bernstein and Avram Brickner

Application No.: 10/689,523 Group Art Unit: 1615

Filed: October 20, 2003 Examiner: Not Assigned

Confirmation No.: 8633

Title: COMPOSITION FOR SUSTAINED RELEASE OF NON-AGGREGATED
ERYTHROPOIETIN

CERTIFICATE OF MAILING OR TRANSMISSION	
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Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

The PRO did not receive the following listed items(s) I confirmed found

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Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application Nos. 08/478,502, 09/001,949 and 09/274,842, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By

Susan M. Abelleira
Susan M. Abelleira

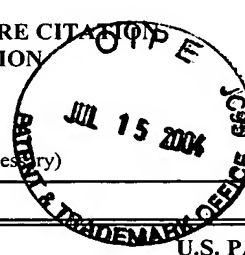
Registration No.: 42,252

Telephone: (978) 341-0036

Facsimile: (978) 341-0136

Concord, MA 01742-9133

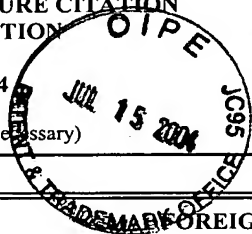
Dated: July 13, 2004

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 1733.1001-017		APPLICATION NO. 10/689,523	
INFORMATION DISCLOSURE CITATIONS IN AN APPLICATION July 13, 2004 (Use several sheets if necessary)				FIRST NAMED INVENTOR Stephen E. Zale	
				FILING DATE October 20, 2003	
EXAMINER Not Assigned				CONFIRMATION NO. 8633	
				GROUP 1615	

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	4,637,905	01/20/87	Gardner
	AB	4,897,268	01/30/90	Tice <i>et al.</i>
	AC	4,767,628	08/30/88	Hutchinson
	AD	4,891,225	01/02/90	Langer <i>et al.</i>
	AE	4,906,474	03/06/90	Langer <i>et al.</i>
	AF	4,711,782	12/08/87	Okada <i>et al.</i>
	AG	4,981,696	01/01/91	Loomis <i>et al.</i>
	AH	4,675,189	06/23/87	Kent <i>et al.</i>
	AI	5,019,400	05/28/91	Gombotz <i>et al.</i>
	AJ	5,126,147	06/30/92	Silvestri <i>et al.</i>
	AK	4,962,091	10/09/90	Eppstein <i>et al.</i>
	AA2	5,192,741	03/09/93	Orsolini <i>et al.</i>
	AB2	4,732,889	03/22/88	Cynshi <i>et al.</i>
	AC2	4,879,272	11/07/89	Shimoda <i>et al.</i>
	AD2	4,992,419	02/12/91	Woog <i>et al.</i>
	AE2	4,806,524	02/21/89	Kawaguchi <i>et al.</i>
	AF2	5,674,534	10/07/97	Zale <i>et al.</i>
	AG2	5,716,644	02/10/98	Zale <i>et al.</i>
	AH2	6,284,283 B1	09/04/2001	Costantino, <i>et al.</i>
	AI2	6,368,630 B1	03/09/2002	Bernstein, <i>et al.</i>
	AJ2			
	AK2			
	AA3			
	AB3			
	AC3			

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 13, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1733.1001-017		APPLICATION NO. 10/689,523	
	FIRST NAMED INVENTOR Stephen E. Zale		FILING DATE October 20, 2003	
	EXAMINER Not Assigned		CONFIRMATION NO. 8633	GROUP 1615



FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	WO 90/09166	23 AUG 90	Biosearch, Inc.		
	AM	WO 90/13780	15 NOV 90	Enzytech, Inc.		
	AN	WO 91/12882	05 SEPT 91	Medgenix Group S.A.		
	AO	WO 92/11844	23 JUL 92	Enzytech, Inc.		
	AP	EP 0537559 A1	01 OCT 92	Atrix Laboratories, Inc.		
	AQ	WO 93/07861	29 APR 93	Board of Regents, The University of Texas System		
	AL2	WO 93/17668	16 SEPT 93	Alkermes Controlled Therapeutics, Inc.		
	AM2	WO 93/25221	23 DEC 93	Alkermes Controlled Therapeutics, Inc.		
	AN2	WO 94/12158	09 JUN 94	Alkermes Controlled Therapeutics, Inc.		
	AO2	WO 96/07399 A1	14 MAR 96	Takeda Chemical Industries, Ltd.		
	AP2					
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				GROUP 1615	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Costantino, H.R., <i>et al.</i> , "Solid-Phase Aggregation of Proteins under Pharmaceutically Relevant Conditions," <i>J of Pharm Sciences</i> , 83(12):1662-1669(1994).
AS	Costantino, H.R., <i>et al.</i> , "Moisture-Induced Aggregation of Lyophilized Insulin," <i>Pharm Res</i> , 11(1):21-29(1994).
AT	Costantino, H.R., <i>et al.</i> , "Aggregation of a Lyophilized Pharmaceutical Protein, Recombinant Human Albumin: Effect of Moisture and Stabilization by Excipients," <i>Biotechnology</i> , 13:493-496(1995).
AU	Creighton, T.E., "Physical Forces That Determine the Properties of Proteins," In <i>Proteins, Structures and Molecular Principles</i> , (NY:W.H.Freeman and Company), pp. 149-150.
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